

Food and Drug Administration Rockville MD 20857

FILICOPY

December 23, 1999

Petur 0. Hansson Bristol-Myers Squibb Company 777 Scudders Mill Road Princeton, NJ 08543-4500

Dear Mr. Hansson:

Your petition requesting the Food and Drug Administration not to finalize the draft guidance for industry entitled "Topical Dermatological Drug Product NDAs and ANDAs -- In Vivo Bioavailability, Bioequivalence, In Vitro Release and Associated Studies", was received by this office on 12/23/99. It was assigned docket number 98D-0388/CP 1 and it was filed on 12/23/99. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Jennie Butler

Dockets Management Branch

98D-0388

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